IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA ALEXANDRIA DIVISION

SARA ALI, *et al.*,	)	
	)	
Plaintiffs	)	
	)	
v.	)	**NO. 1:12-CV-115 (GBL/TRJ)**
	)	
ALLERGAN USA, INC.,	)	
	)	
Defendant.	)	

MEMORANDUM OPINION

THIS MATTER is before the Court on Defendant Allergan USA, Inc.'s ("Allergan") Motion to Dismiss Amended Complaint. This case is brought by a medical patient against the manufacturer of a medical device for an alleged malfunction of the device and for alleged misrepresentations in marketing materials for the device.

There are four issues before the Court. The first issue is whether Plaintiffs Sara and Daniel Ali's ("Plaintiffs") Amended Complaint contains sufficient pleading of claims under Virginia law that are not preempted by the Medical Device Amendments ("MDA") of the federal Food, Drug, and Cosmetic Act ("FDCA"). The Court holds that Plaintiffs' state law claims as pled in the Amended Complaint cannot avoid preemption by the MDA. The Amended Complaint does not present factual allegations demonstrating that the manufacturer, Allergan, violated federal law in the manufacture, labeling, or marketing of the device at issue in this case. Such pleading is required to state "parallel" claims based on state law that do not impose duties

different from or in addition to the federal requirements on the device and thereby avoid preemption. For these reasons, the Court grants Allergan's Motion to Dismiss Amended Complaint as to all causes of action.

The second issue is whether Plaintiffs' fraud claims meet the particularity pleading requirement set forth in Rule 9(b) of the Federal Rules of Civil Procedure. The Court holds that Plaintiffs' cause of action for fraud by negligent misrepresentation is not supported by sufficient pleading of the particular content and circumstances of the alleged misrepresentations to satisfy Rule 9(b). Thus, Plaintiffs' negligent misrepresentation cause of action must be dismissed for insufficient pleading.

The third issue is whether the Virginia Consumer Protection Act ("VCPA") provides a private cause of action for Allergan's alleged misrepresentations about the device where the device is regulated by the FDA. The Court holds that the VCPA does not cover federally regulated medical devices and, therefore, dismisses Plaintiffs' VCPA claims with prejudice.

The fourth issue is whether Plaintiffs' adequately plead false advertising claims under Virginia's false advertising statute. The Court holds that Plaintiffs' false advertising cause of action must be dismissed for Plaintiffs' failure to identify a false promise or statement of fact made by Allergan in advertising for the device.

The Court dismisses the causes of action set forth in the Amended Complaint without prejudice, with the exception of the VCPA cause of action, which is dismissed with prejudice. Plaintiffs may seek leave to amend their pleading and submit an amended pleading for the Court's consideration if they are able to provide sufficient factual matter to state their claims in accordance with this opinion.

I. BACKGROUND

A. Facts Regarding Premarket Approval of the LAP-BAND by the FDA

Pursuant to Rule 201 of the Federal Rules of Evidence, and upon Allergan's motion, the Court takes judicial notice of several documents issued by the United States Food and Drug Administration ("FDA") and Department of Health and Human Services ("HHS").[1] These documents, presented in Allergan's Exhibits A, C, E, and F, pertain to FDA approval of the LAP-BAND Adjustable Gastric Banding System ("LAP-BAND"),[2] the medical device at issue in this case. The Court considers the facts presented in these documents in connection with Defendant's Motion to Dismiss Amended Complaint.

The LAP-BAND is a Class III medical device[3] manufactured and marketed by Allergan. "The device is a permanent implant placed around the upper portion of the stomach to reduce the

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[1] Rule 201(b)(2) provides that federal courts may take judicial notice of "a fact that is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." FED. R. EVID. 201(b)(2) (2012). Rule 201(c)(2) requires the court to take judicial notice of such a fact "if a party requests it and . . . supplie[s the court] with the necessary information." FED. R. EVID. 201(c)(2). A court must consider judicially noticed facts in assessing the sufficiency of a complaint and a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

[2] Exhibit A is a letter from HHS granting premarket approval ("PMA") for the LAP-BAND, which includes the conditions of the PMA. Exhibit C is a Summary of Safety and Effectiveness Data prepared by the Center for Devices and Radiological Health ("CDRH") of the FDA. Exhibit E is a letter from HHS to Allergan approving a PMA supplement for the LAP-BAND. Exhibit F is an Executive Summary Memorandum regarding the LAP-BAND for the FDA's Gastroenterology and Urology Devices Advisory Panel.

[3] There are three regulatory classes of medical devices intended for human use.

> A device is in class III if insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness or that application of special controls . . . would provide such assurance and if, in addition, the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

21 C.F.R. § 860.3(c)(3) (2012); *see also* 21 U.S.C. § 360c(a)(1)(C). Class III devices require premarket approval by the FDA pursuant to section 515 of the Food, Drug, and Cosmetic Act ("FDCA"), codified at 21 U.S.C. § 360e.

amount of food that can be ingested[,] resulting in reduced calorie intake and weight loss." Def.'s Ex. F at 3; *see also* Def.'s Ex. C at 7. It is "restricted to prescription use" and "indicated for use only in severely obese patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise and behavior modification programs." Def.'s Ex. A at 1, 3. In 2001, the CDRH determined that there was sufficient pre-clinical and clinical data establishing the safety and effectiveness of the LAP-BAND to warrant FDA approval. Def.'s Ex. C at 24. The FDA approved the device "for use in weight reduction for severely obese patients . . . in accordance with its labeling." *Id.* at 23.

Contemporaneously with its approval of the LAP-BAND, the FDA noted several potential adverse effects of the device on health, including the risk that the band would erode while implanted. *Id.* at 9-10. The FDA determined that 89% of subjects in the United States clinical trial reported at least one adverse event, though "[m]any adverse events were mild and required no intervention." *Id.* at 10. Only 1% of subjects experienced band erosion, which was "resolved with explantation of the device" in each case. *Id.* at 22; *see also* Def.'s Ex. F at 11 (band erosion as "a potentially serious complication" but "infrequent in occurrence"). The FDA issued several warnings and precautions concerning use of the LAP-BAND, including warnings that "[e]xplant and replacement surgery may be indicated at any time" as well as warnings specifically about the risk of band erosion. Def.'s Ex. C at 2–7. The FDA warned of several ways that the risk of band erosion could be increased, including the use of anti-inflammatory agents by the patient and certain surgical procedures. *Id.*

Pursuant to section 515 of the Food, Drug, and Cosmetic Act ("FDCA"), codified at 21 U.S.C. § 360e, the LAP-BAND first obtained FDA premarket approval ("PMA") for commercial distribution on June 5, 2001, subject to certain ongoing conditions. Def.'s Ex. F at 5; *see also*

Def.'s Ex. A. These conditions include restrictions on the labeling of the device to that specifically approved by the FDA. Defs.'s Ex. A at 1, 3. The FDA also prohibits advertisements and other descriptive material recommending or implying that the LAP-BAND may be used in any way not included in the FDA-approved labeling for the device. *Id.* at 3. Importantly, the manufacturer is required to submit a PMA supplement for FDA review and approval before making any change or modification to the LAP-BAND, which might affect its safety or effectiveness. *Id.*; *see also* Def.'s Ex. E at 3. The modified device is subjected to testing to determine whether it remains safe and effective. Defs.'s Ex. A at 3; *see also* 21 C.F.R. § 814.82(a)(2) (2012).

The manufacturer is also required to submit annual post-approval reports identifying changes to the device affecting its safety or effectiveness, labeling changes, new indications for use of the device, changes in the performance or design of the device, the use of a different manufacturing or packaging facility, and similar changes. Defs.'s Ex. A at 4; *see also* 21 C.F.R. § 814.39. Published and unpublished reports or studies on the device must be identified and summarized in these annual reports. Defs.'s Ex. A at 4. The manufacturer must also prepare and submit to the FDA reports of adverse reactions, device defects, and any corrective action taken to address such problems. *Id.* at 5, 6; *see also* 21 C.F.R. §§ 803.50–803.52.

Since the initial PMA of the LAP-BAND, the device has obtained FDA approval of PMA supplements, and the conditions of approval remain in effect. *See* Def.'s Ex. E. Allergan has most recently agreed to conduct post-approval studies to evaluate the long-term effectiveness of the LAP-BAND and the incidence of adverse effects. *Id.* at 2.

B. Facts Alleged in the Amended Complaint

Plaintiffs allege the following facts in their Amended Complaint.

On December 17, 2009, Sara Ali underwent bariatric surgery at the Inova Fair Oaks Hospital located in Fairfax, Virginia. Am. Compl. ¶ 18. During Ms. Ali's surgery, a LAP-BAND manufactured and marketed by Allergan was surgically inserted in her, and Ms. Ali was discharged on December 21, 2009. *Id.* at ¶ 19. On December 23, 2009, Ms. Ali was admitted to Reston Hospital Center in Reston, Virginia, complaining of difficulty breathing and swallowing, and it was determined that she required a second surgery. *Id.* at ¶ 20. During this second surgery, the original LAP-BAND was explanted and replaced by another LAP-BAND, which was also manufactured and marketed by Allergan. *Id.*

On April 15, 2011, Ms. Ali was admitted to Inova Fair Oaks Hospital again because she was experiencing severe abdominal pain in her lower abdominal quadrant. *Id.* at ¶ 21. On April 19, 2011, an esophagogastroduodenoscopy ("EGD") was performed on Ms. Ali, and it was determined that the LAP-BAND implanted on December 23, 2009, had eroded. *Id.* The LAP-BAND was surgically removed on April 20, 2011, by Dr. Hazim Elariny. *Id.* at ¶ 22. During the surgery, Dr. Elariny discovered a dense extensive inflammatory mass extending from the left upper quadrant to the right lower quadrant surrounding the tubing of the LAP-BAND, phlegmon formation, and multiple abscesses. *Id.* at ¶ 23. Dr. Elariny performed a blunt dissection and electrocautery of the inflammatory mass, a gastronomy involving removal of the LAP-BAND, and a saline washing and draining of the abdominal cavity. *Id.* at ¶ 24. Ms. Ali suffered and continues to suffer from complications arising from the erosion of the LAP-BAND. *Id.* at ¶ 25.

Plaintiffs allege that, in electing the implantation of the LAP-BAND as a weight loss measure, Ms. Ali and her physician relied upon representations made by Allergan in its labeling and marketing of the device that turned out to be false. *Id.* at ¶ 27. These representations included the following, *inter alia*: the LAP-BAND was tested and found to be safe and effective; the

LAP-BAND was the safest and healthiest weight loss surgery; the LAP-BAND had the lowest operative complication rate of all weight loss surgeries; and the LAP-BAND had ten times lower short-term mortality rate than gastric bypass. *Id.* Plaintiffs also allege that Allergan's representations that "the LAP-BAND would be manufactured in accordance with FDA regulations" and "would not malfunction" were "part of the basis of the bargain," but these representations were false. *Id.* at ¶¶ 88–89.

C. Procedural History

On November 9, 2011, Ms. Ali and her husband Daniel Ali brought suit against Allergan in the Supreme Court of New York, County of New York. On December 14, 2011, Allergan removed the case to the United States District Court for the Southern District of New York. On February 2, 2012, upon Allergan's motion, the case was transferred to the Eastern District of Virginia. On March 9, 2012, Plaintiffs filed their Amended Complaint, setting forth seven causes of action against Allergan under Virginia law: (1) fraud by negligent misrepresentation; (2) fraud by nondisclosure; (3) negligence; (4) breach of express warranty; (5) breach of implied warranty; (6) violation of Virginia Consumer Protection Act; and (7) violation of Virginia's false advertising statute. On March 12, 2012, Allergan filed its Motion to Dismiss Amended Complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure, which Plaintiffs opposed. The Court heard oral argument on March 23, 2012.

II. STANDARD OF REVIEW

A motion to dismiss a complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure should be granted unless the complaint "states a plausible claim for relief" under Rule 8(a). *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S.

544, 563 (2007)); *see also* FED. R. CIV. P. 8(a)(1), 12(b)(6). In considering a Rule 12(b)(6) motion, the Court must construe the complaint in the light most favorable to the plaintiff, read the complaint as a whole, and take the facts asserted therein as true. *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1134 (4th Cir. 1993). In addition to the complaint, the court may also examine "documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

The general pleading standard provided in Rule 8(a) requires that the complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555 (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)) (internal quotation marks omitted); *see also* FED. R. CIV. P. 8(a)(2). In *Bell Atlantic Corp. v. Twombly*, the United States Supreme Court held that the "plain statement" must "possess enough heft"—that is, "factual matter"—to set forth grounds for the plaintiff's entitlement to relief and "to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 557, 570. The complaint must contain sufficient factual allegations, taken as true, "to raise a right to relief above the speculative level," *id.* at 555, and "across the line from conceivable to plausible," *id.* at 570. The Court explained further, in *Ashcroft v. Iqbal*, that the standard of facial plausibility requires pleading of "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). The complaint must present "enough fact to raise a reasonable expectation that discovery will reveal evidence of [the alleged misconduct]." *Twombly*, 550 U.S. at 556.

"A pleading that offers labels and conclusions[,] a formulaic recitation of the elements of a cause of action[,]" or "naked assertions devoid of further factual enhancement" will not suffice.

Iqbal, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555, 557) (internal quotation marks omitted). "[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Iqbal*, 556 U.S. at 678; *see also Labram v. Havel*, 43 F.3d 918, 921 (4th Cir. 1995) ("conclusory allegations regarding the legal effect of the facts alleged" need not be accepted as true).

In *Iqbal* and *Twombly*, the Supreme Court demonstrated a two-step approach to assessing the sufficiency of a complaint: (1) "identify[] the allegations in the complaint that are not entitled to the assumption of truth"; and (2) "consider the factual allegations in [the] complaint to determine if they plausibly suggest an entitlement to relief." *Iqbal*, 556 U.S. at 680-81. Thus, in order to survive a Rule 12(b)(6) motion to dismiss, the complaint must present sufficient non-conclusory factual allegations to support reasonable inferences of the plaintiff's entitlement to relief and the defendant's liability for the unlawful act or omission alleged.

Fraud claims are subject to a heightened pleading standard. *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 783–84 (4th Cir. 1999). Under Rule 9(b), "a party [alleging fraud or mistake], must state with particularity the circumstances constituting fraud or mistake." FED. R. CIV. P. 9(b). "[T]he 'circumstances' required to be pled with particularity under Rule 9(b) are 'the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby.'" *Harrison*, 176 F.3d at 784 (quoting 5 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1297 (2d ed. 1990)). Failure to comply with pleading standard set forth in Rule 9(b) where applicable constitutes failure to state a claim and is therefore grounds for dismissal of a fraud claim under Rule 12(b)(6). *Harrison*, 176 F.3d at 783 n.5.

III. ANALYSIS

The Court grants Allergan's Motion to Dismiss Amended Complaint because Plaintiffs' causes of action, as pled in the Amended Complaint, are preempted by the Medical Device Amendments ("MDA") to the FDCA. The MDA expressly preempt requirements imposed by state law on the safety and effectiveness of a medical device that are "different from, or in addition to, any requirement applicable . . . to the device" under the FDCA. 21 U.S.C. § 360k(a) (2012).

In *Riegel v. Medtronic, Inc.*, the Supreme Court considered whether common law claims, brought under New York law, challenging the safety of a premarket approved Class III medical device were preempted under 21 U.S.C. § 360k(a). 552 U.S. 312, 321-22 (2008). The Court held first that the FDA's premarket approval ("PMA") process imposes federal "requirements" within the meaning of § 360k(a). *Id.* at 322-23. The Court noted that PMA may only be granted after the FDA determines that the specific device "offers a reasonable assurance of safety and effectiveness" upon extensive review of relevant data and statements describing the device and the manufacturing process in depth. *Id.* at 317-18, 323. Additionally, PMA is granted only upon the condition that the device bear the FDA-approved label containing required disclosures and that the device be manufactured "with almost no deviations from the specifications in its approval application." *Id.* at 322-23. As such, PMA imposes "requirements" that are "specific to individual devices," and therefore preempts requirements established or enforced by a state that differ from or add to requirements imposed through FDA regulation. *Id.*

Second, the Court held that the reference in § 360k(a) to requirements established or enforced by a state includes common-law duties imposed by state law. *Id.* at 324. The Court reasoned that state law that requires a premarket approved Class III device "to be safer, but

hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect." *Id.* at 325. Thus, claims brought under state common law that impose requirements on the manufacture or labeling of a premarket approved medical device that differ from or add to federal requirements on the device imposed through the FDA regulation are preempted under § 360k(a). *Id.* at 330; *see also Walker v. Medtronic, Inc.* (*Walker II*), 670 F.3d 569, 577 (4th Cir. 2012).

In *Medtronic, Inc. v. Lohr*, however, the Supreme Court held that § 360k(a) does not preclude a state from "provid[ing] a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." 518 U.S. 470, 495 (1996). State-law requirements that are parallel to federal requirements are those that impose "duties equal to, or substantially identical to, requirements imposed under federal law." *Id.* at 496–97 (internal quotation marks omitted), *cited in Riegel*, 522 U.S. at 330. Rather than imposing requirements that differ from or add to federal requirements, parallel claims based on violations of state-law duties are "premised on" violations of federal requirements. *Riegel*, 522 U.S. at 330; *see also Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 770 (5th Cir. 2011) (state tort claims "premised entirely on violation of the applicable federal requirements" are not preempted).

In light of *Riegel* and *Lohr*, federal courts in various circuits have held that, in order to adequately plead a parallel state-law claim and avoid § 360k(a) preemption, a plaintiff must allege a violation of federal regulations with sufficient facts to render the alleged violation plausible under *Twombly* and *Iqbal*. *See, e.g.*, *Bass v. Stryker Corp.*, 669 F.3d 501, 509 (5th Cir. 2012); *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation* (*Medtronic Leads II*), 623 F.3d 1200, 1203 (8th Cir. 2010); *Covert v. Stryker Corp.*, No. 1:08CV447, 2009 WL 2424559, at *14 (M.D.N.C. Aug. 5, 2009); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301

(D. Colo. 2008). Thus, conclusory allegations that the defendant violated FDA regulations in the manufacture, labeling, or marketing of the premarket approved medical device are insufficient to state a parallel state-law claim and thereby avoid preemption under § 360k(a). *Parker*, 584 F.Supp.2d at 1301. *See also Gelber v. Stryker Corp.*, 752 F. Supp. 2d 328, 334 (S.D.N.Y. 2010); *In re Medtronic, Inc., Sprint Fidelis Leads Product Liability Litigation* (*Medtronic Leads I*), 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009), *aff'd*, *Medtronic Leads II*, 623 F.3d 1200 ("Plaintiffs cannot simply incant the magic words '[defendant] violated FDA regulations' in order to avoid preemption.").

In this case, Plaintiffs' causes of action, as pled in the Amended Complaint, are preempted under 21 U.S.C. § 360k(a). The LAP-BAND is a Class III medical device that has obtained PMA by the FDA. Under the § 360k(a), Virginia law cannot impose duties on Allergan in the manufacture, labeling, or marketing of the device unless those duties parallel—*i.e.*, are "equal to, or substantially identical to"—requirements imposed on the device by federal regulations. *Lohr*, 518 U.S. at 496–97 (internal quotation marks omitted). Thus, in order to avoid preemption under § 360k(a), Plaintiffs' claims challenging the manufacture, marketing, and labeling of the device as these pertain to the safety and effectiveness of the device must be premised on violations of federal regulations. *Riegel*, 522 U.S. at 330. Plaintiffs fail to plead sufficient facts to show that Allergan violated federal law in the manufacture, labeling, or marketing of the LAP-BAND device. The Amended Complaint offers a series of conclusory allegations that that Allergan violated federal law in the manufacture and marketing of the LAP-BAND. However, without factual enhancement, these statements are insufficient to plead plausible federal violations by Allergan. *See Iqbal*, 556 U.S. at 678. For this reason, Plaintiff's

causes of action for negligence, breach of warranty, fraud, and false advertising must be dismissed without prejudice.

Additionally, Plaintiffs' causes of action for fraud, false advertising, and violations of the Virginia Consumer Protection Act ("VCPA") must be dismissed for other reasons as well. The cause of action for fraud by negligent misrepresentation must be dismissed for Plaintiffs failure to plead with particularity the content and circumstances of Allergan's alleged misrepresentations, as required by Rule 9(b). Plaintiffs' false advertising claims must be dismissed because Plaintiffs fail to identify any false promise or statement of fact made by Allergan in advertising the LAP-BAND device. Plaintiffs' VCPA claims are dismissed with prejudice because the statute does not cover transactions in prescription medical devices regulated by the FDA.

A. Negligence and Breach of Implied Warranty

The Court grants Allergan's Motion to Dismiss with respect to Plaintiffs' causes of action for breach of implied warranty and negligence because Plaintiffs fail to plead sufficient facts to support the inference that the LAP-BAND was manufactured in a way that deviated from federal requirements. Without sufficient pleading that Plaintiffs' state-law breach of implied warranty and negligence claims impose duties parallel to federal regulations, these claims are preempted by 21 U.S.C. § 360k(a).

Under Virginia law, a plaintiff may recover for personal injuries caused by defective products under either a negligence theory or as a breach of an implied warranty of merchantability. *Abbot by Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108, 1114 (4th Cir. 1988). "The essential elements of a negligence claim in Virginia . . . are (1) the identification of a legal duty of the defendant to the plaintiff; (2) a breach of that duty; and (3) injury to the plaintiff

proximately caused by the breach." *Talley v. Danek Med., Inc.*, 179 F.3d 154, 157 (4th Cir. 1999). Virginia law imposes a duty on manufacturers to exercise ordinary care in making their products reasonably safe. *Carney v. Sears, Roebuck & Co.*, 309 F.2d 300, 304 (4th Cir. 1962). "The standard of safety of goods imposed on the seller or manufacturer of a product is essentially the same whether the theory of liability is labeled warranty or negligence." *Logan v. Montgomery Ward & Co.*, 219 S.E. 2d 685, 687 (Va. 1975).

> Under either the warranty theory or the negligence theory[,] the plaintiff must show: (1) that the goods were unreasonably dangerous either for the use to which they would ordinarily be put or for some other reasonably foreseeable purpose; and (2) that the unreasonably dangerous condition existed when the goods left the defendant's hands.

Id. "Products are 'unreasonably dangerous' if they are (1) defective in assembly or manufacture; (2) imprudently designed; or (3) not accompanied by adequate warnings about their hazardous properties." *Austin v. Clark Equip. Co.*, 821 F. Supp. 1130, 1133 (W.D. Va. 1993) (citing *Bly v. Otis Elevator Co.*, 713 F.2d 1040, 1043 (4th Cir. 1983)).

Claims brought under state law attacking as unsafe the federally approved design and manufacture of Class III medical devices are preempted by the MDA as imposing requirements that differ from or add to federal requirements. *Riegel*, 522 U.S. at 324-25; *see also* 12 U.S.C. § 360k(a). In order to recover for injuries caused by a manufacturing defect in a premarket approved medical device on state law grounds, the applicable state law must impose duties on a device manufacturer that are equal or parallel to federal requirements. *Riegel*, 522 U.S. at 330. In order to state such a parallel claim, the plaintiff must allege sufficient facts to support both the inference that the defendant manufactured the device in a way that violated federal regulations and the inference that this violation resulted in the defect that caused the plaintiff's injuries. *Bass v. Stryker Corp.*, 669 F.3d 501, 515, 517 (5th Cir. 2012); *see also Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301-02 (11th Cir. 2011).

Since the Supreme Court's decision in *Riegel*, federal courts have required plaintiffs asserting state-law claims based on manufacturing defects to plead facts showing violations of federal manufacturing requirements in ways that have resulted in the defect at issue. Recently, in *Bass v. Stryker Corp.*, the Court of Appeals for the Fifth Circuit considered whether a complaint adequately pled parallel negligence, implied warranty, and other claims brought under Texas law where the plaintiff allegedly suffered personal injuries as a result of a defective component in a premarket approved hip replacement system. *Bass*, 669 F.3d at 508-18. Citing a number of post-*Riegel* decisions of courts in various federal circuits, the court held that, in order "to plead a parallel claim successfully, a plaintiff's allegations that the manufacturer violated FDA regulations must meet the *Twombly* plausibility standard." *Id.* at 509. Specifically, the court held that the plaintiff meets the plausibility standard with respect to federal violations in manufacturing where the plaintiff identifies "what went wrong in the manufacturing process and cites the relevant FDA manufacturing standards [that were] allegedly violated." *Bass*, 669 F.3d at 510 (quoting *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011)). The plaintiff adequately pled parallel negligent manufacturing claims because his allegations supported the inference the defendants violated FDA manufacturing requirements and that these violations resulted in the defect that caused the plaintiff's injuries.[4] *Id.* at 510, 515.

[4] In *Bass*, the plaintiff alleged that the defective component of the device at issue was adulterated in violation of specifically identified federal regulations, and offered facts to support this claim. *Bass*, 669 F.3d at 510. According to the complaint, the FDA had recently issued a warning letter noting the defendant manufacturers' failure to take measures to reduce bioburden (microbial contaminant) at a specific point in the manufacturing process (the final rinse tank). *Id.* More specifically, "[the plaintiff] pleaded that excess bioburden . . . and manufacturing residuals on the [component at issue] are known to prevent bony ingrowth, resulting in [the specific injury alleged by the plaintiff]." *Id.* The plaintiff also alleged that the defendants initiated a recall on the component at issue after the FDA issued the warning letter. *Id.* These factual allegations were sufficient to render plausible the plaintiff's claim that the defendants violated FDA regulations in the manufacturing process and that these violations resulted in the defect that caused the plaintiff's injuries. *Id.*

The *Bass* court required pleading with a comparable level of factual support with respect to the plaintiff's breach of implied warranty claims. *Id.* at 561-17. After reviewing several pre- and post-*Riegel* decisions on the issue, the court determined that most post-*Riegel* cases that found preemption "concluded that the claims failed to rely on violations of the FDA's requirements, or the plaintiff pleaded that the defendants complied with the FDA's requirements." *Id.* at 517 (citing, *e.g.*, *Walker v. Medtronic, Inc.* (*Walker I*), Civil Action No. 2:07-00317, 2010 WL 4822135 (S.D. W.Va. Nov. 24, 2010), *aff'd*, 670 F.3d 569 (4th Cir. 2012)). Ultimately, the court held that "an implied warranty claim is not preempted if the plaintiff alleges that the defendant violated federal requirements *and* can ultimately show a causal link between the violation and the breach of the implied warranty." *Bass*, 669 F.3d at 517. The plaintiff's implied warranty claims were not preempted and survived the defendants' motion to dismiss "to the extent that [they were based] on violations of federal requirements," which had been sufficiently pled.[5] *Id.*

The Fifth Circuit is not alone in applying the *Twombly* plausibility standard to allegations that a manufacturer has violated the terms of its PMA or other federal requirements applicable to their devices. *See, e.g.*, *Wolicki-Gables*, 634 F.3d at 1301 ("plaintiff must allege that '[the] defendant violated a particular federal specification referring to the device at issue'" (quoting *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009))); *Parker*, 584 F. Supp. 2d at 1301 ("[T]he complaint must set forth facts showing 'action or inaction in defendants' efforts to take part in the PMA process or implement its results.'" (quoting *Heisner ex rel. Heisner v. Genzyme Corp.*, No. 08-C-593, 2008 WL 2940811, at *5 (N.D. Ill. July 25, 2008))); *Delaney v. Stryker Orthopaedics*, Civil Action No. 08-03210, 2009 WL 564243, at *6 (D.N.J.

[5] *See supra* note 4.

Mar. 5, 2009) (dismissing manufacturing defect claim where "[c]omplaint d[id] not specify in what way [the manufacturer] deviated from the manufacturing process that the FDA approved").

Additionally, like the Fifth Circuit, several courts have held that, in order to adequately plead a parallel claim based on a manufacturing defect, the complaint must contain sufficient facts to support the inference that the defendant's federal violations resulted in the defect that caused the plaintiff's injuries. *See, e.g.*, *Parker*, 584 F.Supp.2d at 1301 (dismissing parallel claims as inadequately pled because the "plaintiff d[id] not allege that [the defendant's] failure to comply with [federal] regulations rendered [the device at issue] defective"); *Gelber*, 752 F. Supp. 2d at 334 (dismissing product liability claims where plaintiffs "have not pointed to evidence of device-specific violations of federal law or alleged how those violations have a cognizable link to [plaintiffs'] injuries"); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 282 (E.D.N.Y. 2009) ("[I]n order to survive preemption under the MDA[,] a plaintiff must demonstrate a cognizable link between the defendant's federal violations and [the] plaintiff's injury."). *Cf. Wolicki-Gables*, 634 F.3d at 1301-02 (affirming district court's finding of preemption of product defect claims at summary judgment stage where plaintiffs did not show defendant's noncompliance "with any FDA regulation that can be linked to the injury alleged" (quoting *Ilarraza*, 677 F. Supp. 2d at 589)).

In applying the facial plausibility standard, courts have required varying levels of factual detail in the pleading of federal violations in connection with defective manufacturing of premarket approved medical devices. *Compare Medtronic Leads I*, 592 F. Supp. 2d at 1153, 1157-58 (dismissing manufacturing defect claims where plaintiffs identified the defect and the federal standards violated but failed to plead "factual detail about *why*" the defect violated the standards, which the court characterized as flexible and generic), *with Bausch v. Stryker Corp.*,

630 F.3d 546, 559-60 (7th Cir. 2010) (pleading "the precise defect [and] the specific federal regulatory requirements that were allegedly violated" was not required where plaintiff alleged that an FDA inspection revealed "numerous deficiencies" in the manufacturing process, an FDA warning letter stated that the device was "adulterated due to manufacturing methods . . . not in conformity with industry and regulatory standards," and the defective device bore "the same catalogue number as the device allegedly not in compliance with regulations").[6] However, it is clear from the majority of post-*Riegel* cases that "[p]laintiffs cannot simply incant the magic words '[the defendant] violated FDA regulations' in order to avoid preemption." *Gelber*, 752 F. Supp. 2d at 334 (quoting *Medtronic Leads I*, 592 F.Supp.2d at 1158); *see also Parker*, 584 F. Supp. 2d at 1301 ("[C]onclusory allegations standing alone are not sufficient to sustain plaintiff's burden of pleading under *Twombly*."). Plaintiffs asserting state-law claims based on manufacturing defects in premarket approved medical devices must plead sufficient facts to support inferences that the defendant manufacturer violated federal requirements and that these violations were linked to the alleged defect.

Here, Plaintiffs' negligence and implied warranty claims are preempted by the MDA for insufficient pleading of a federal violation by Allergan. Plaintiffs' negligence and implied warranty claims ultimately challenge Allergan's manufacture of a LAP-BAND implant, a Class

[6] Judge Melloy dissented from the Eighth Circuit's decision in *Medtronic Leads II* to affirm dismissal of the plaintiffs' manufacturing defect claims. *Medtronic Leads II*, 623 F.3d 1200 at 1209-10 (Melloy, J., concurring in part and dissenting in part). He argued that "the specificity requirements of *Twombly* must be applied in a practical manner that recognizes the parties' relative access to information necessary to articulate claims with specificity." *Id.* at 1209. Applying a relaxed *Twombly* standard in this context, Judge Melloy would permit discovery of the confidential PMA files for the device at issue and, after discovery, require the plaintiffs to amend their pleading with more facts. *Id.* at 1209-10. Judge Melloy "emphasiz[ed] that the requested discovery would be quite limited and impose virtually no burden on the defendants." *Id.* at 1210. In *Bausch*, the Seventh Circuit voiced agreement with Judge Melloy's dissent. 630 F.3d at 552-54. Considering the plaintiff's lack of access to the defendant's PMA documents, the court determined that the plaintiff had sufficiently pled parallel tort claims "given the amount of information to which she had access." *Id.* at 561.

III medical device that has obtained PMA by the FDA. However, the Amended Complaint does not present sufficient factual content to support an inference that Allergan violated federal law in the manufacture of the LAP-BAND or that any such violation caused Ms. Ali's injuries. Without a federal violation, Plaintiffs' claims impose duties on Allergan, under Virginia law, that differ from or add to federal requirements on the manufacture of the device, and are therefore preempted by 21 U.S.C. § 360k(a).

Plaintiffs allege "[u]pon information and belief" that, in manufacturing the device at issue here, Allergan violated various federal statutes, regulations, and standards, including the following: the FDCA and, specifically, 21 U.S.C. § 360k; "any regulations promulgated pursuant to the Act"; the terms and conditions of the PMA secured for the LAP-BAND; and Current Good Manufacturing Practices and Quality Systems Regulation. Am. Compl. ¶¶ 70–79. Identifying the specific provisions of federal law allegedly violated by Allergan would have aided the pleading if Plaintiffs provided facts demonstrating these violations. However, without factual enhancement, Plaintiffs' series of legal conclusions is insufficient to meet the requirements of Rule 8(a).

Even where Plaintiffs' allegations of Allergan's violations appear to acquire some factual matter, they are revealed, upon examination to be simple recitations of regulatory language. For instance, Plaintiffs' allegation that Allergan "failed to establish and maintain procedures for monitoring to control its product that did not conform to specified requirements, in violation of 21 CFR § 820.70 *et seq.*," *id.* at ¶ 75, closely tracks the language of 21 C.F.R. § 820.70(a). Such recitations of regulatory language are no more entitled to the assumption of truth than pure legal conclusions. Similarly, Plaintiffs' allegation that the LAP-BAND was "adulterated," is a naked assertion based on nothing but conclusory allegations of Allergan's failure to comply with

"performance standards" and "federal requirements." *Id.* at ¶ 70. This statement, therefore, is not entitled to the assumption of truth.

Setting aside naked assertions and conclusory allegations of federal violations leaves no pleading that Allergan violated the terms of its PMA or any federal law in the manufacture of the medical device at issue in this case. The facts alleged about Ms. Ali's surgeries and injuries provide no indication of any federal violation by Allergan. First, Plaintiffs allege that, in 2009, a LAP-BAND manufactured by Allergan was implanted in Ms. Ali that ultimately needed to be explanted and replaced by another LAP-BAND, also manufactured by Allergan. *Id.* at ¶¶ 19–20. Second, Plaintiffs allege that, in 2011, Ms. Ali suffered severe abdominal pain caused by the erosion of the second LAP-BAND, which was detected by EDG. *Id.* at ¶ 21. Third, Plaintiffs allege that Ms. Ali underwent a surgical procedure during which the eroded LAP-BAND was removed and her abdominal cavity was treated, but she continues to suffer injuries caused by the eroded LAP-BAND. *Id.* at ¶¶ 22-25. Plaintiffs allege further that that the LAP-BAND that eroded had reached Ms. Ali and her implanting physician "without substantial change in the condition in which it was manufactured and sold by [Allergan]." *Id.* at ¶ 92. These facts are sufficient to support the inference of a causal link between the erosion of the LAP-BAND and Ms. Ali's injuries but are not sufficient to link the erosion or Ms. Ali's injuries to any federal violation by Allergan in the manufacture of the device.

Moreover, the allegation that the second LAP-BAND eroded does not, by itself, suggest that Allergan violated federal requirements in manufacturing this device. At the time the LAP-BAND obtained PMA, the FDA was aware of the LAP-BAND's risk of erosion and the risk that erosion could cause serious complications. Def.'s Ex. C at 22; Def.'s Ex. F at 11. The FDA was also aware that the risk of band erosion could be increased by the patient's use of anti-

inflammatory agents and by certain surgical procedures. Def.'s Ex. C at 2–7. Ultimately, the FDA determined that band erosion was a rare occurrence and that serious complication resulting from band erosion was an even rarer occurrence, and approved the device despite these risks. Def.'s Exs. A, E. Plaintiffs' offer no indication that erosion reflects any noncompliance with federal requirements on the manufacture of the LAP-BAND.

No indication of any federal violation by Allergan in connection with the manufacture of the eroded LAP-BAND is offered in Plaintiffs' remaining allegations. Plaintiffs' allegation that, in 2000, initial efforts to obtain PMA for the device failed cannot support an inference of any federal violation in connection with the LAP-BAND at issue in this case. The device obtained PMA more than eight years before it was first implanted in Ms. Ali's body, and the manufacture of the device has been subject to the terms of its PMA since that time. Plaintiffs' allegation that, in 2010, Allergan recalled nine models of the device is also insufficient. They do not allege that the model of the LAP-BAND that allegedly caused Ms. Ali's injuries in 2011 was among the models recalled in 2010 or that these models were recalled due to any manufacturing defect or erosion issue. Thus, Plaintiffs allege no facts supporting the inference of any such federal violation or causal connection to Plaintiffs' injuries, and therefore fail to state facially plausible parallel claims for relief.

The only federal post-*Riegel* case Plaintiffs cite that support of their negligence and implied warranty claims is the decision of the District Court for the Southern District of Indiana in *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830 (S.D. Ind. 2009). Mem. in Opp'n, at 11, 16. In *Hofts*, the district court denied a motion to dismiss defective manufacture, implied warranty, and other state-law claims based on alleged defects in a premarket approved Class III medical device. *Hofts*, 597 F. Supp. 2d at 841. The complaint alleged that the device at issue was

"unreasonably dangerous and defective" and that the manufacturing process for the device "did not satisfy the FDA's PMA standards." *Id.* at 836 (quoting complaint). The plaintiff also alleged that the device had an "impurity, imperfection, and/or another product defect [that] was a deviation from [the defendant's] design and quality manufacturing standards for the [device] approved by the FDA." *Hofts*, 597 F. Supp. 2d at 836 (quoting complaint).

The court held that these conclusory allegations and naked assertions were "sufficient to satisfy [the plaintiff's] obligation to put [the defendant] on notice of the nature of his claim and to plead enough facts to state a plausible claim to relief" under *Twombly*. *Hofts*, 597 F. Supp. 2d at 841. Specifically, the *Hofts* court found that the plaintiff's defective manufacture tort claims were based on "allegations that [the defendant] failed in its obligation to meet the FDA's requirements," and rejected the defendant's preemption argument on this basis. *Hofts*, 597 F. Supp. 2d at 838; *see also Riegel*, 522 U.S. at 330 (state-law claims that are "premised on" violations of federal requirements do not impose requirements that differ from or add to federal requirements and, therefore, are not preempted by the MDA). The court also rejected the preemption argument with respect to the plaintiff's breach of implied warranty claim because the defendant failed to demonstrate that the claim was based on "standards other than those permitted by the FDA" and therefore failed to establish MDA preemption. *Hofts*, 597 F. Supp. 2d at 840.

This Court respectfully disagrees with the *Hofts* court's application of the Rule 8 pleading standard. In denying the motion to dismiss as to the plaintiff's defective manufacture claims, the *Hofts* court decried as "an unusually stringent application of *Twombly* and Rule 8" the Minnesota district court's decision in *Medtronic Leads I. Id. Compare Medtronic Leads I*, 592 F.Supp.2d at 1158. This Court finds the *Hofts* court unusually lax in its application of the

standard. In assessing the sufficiency of pleadings, district courts should not take conclusory allegations as true but must require factual support for any legal conclusions offered in pleadings. *Iqbal*, 556 U.S. at 678. Requiring such factual enhancement does not constitute a heightened pleading standard; it is the basic pleading standard established in Rule 8 as interpreted in *Twombly* and *Iqbal*. Without factual allegations supporting inferences of the defendant's liability and the plaintiff's right to relief, pleadings fail to provide adequate notice of the grounds upon which the plaintiff's claim rests. *Twombly*, 550 U.S. at 557, 570. In *Hofts*, the district court relaxed the facial plausibility standard out of existence with respect to the plaintiff's allegations that the defendant violated federal requirements. This Court declines to adopt that approach in the context of this case. *See Desabio v. Howmedica Osteonics Corp.*, 817 F.Supp.2d 197, 204 (W.D.N.Y. 2011) (disagreeing with *Hofts* regarding the application of *Twombly* and Rule 8).

This Court also respectfully disagrees with the *Hofts* court's approach to the breach of implied warranty claim, where the court placed the burden on the defendant to show that the claim imposed standards different from applicable federal requirements. *See Hofts*, 597 F. Supp. 2d at 840. Rule 8 places the burden of pleading a plausible claim for relief and the grounds for this claim on the claimant. *Twombly*, 550 U.S. at 555. In order to avoid MDA preemption, state-law claims based on an alleged manufacturing defect in a premarket approved medical device must also be based on a violation of applicable federal manufacturing requirements. *Riegel*, 522 U.S. at 330. Thus, in order to adequately set forth the grounds for such a claim, the claimant must plead a federal violation. This Court agrees with the majority of federal courts in holding, post-*Riegel*, that the facial plausibility standard applies to the pleading of a federal violation in this context and requires facts indicating noncompliance with federal requirements on the

manufacture of the device. In applying the facial plausibility standard here, the Court holds that the Amended Complaint fails to set forth sufficient factual allegations to support the inference that Allergan violated federal requirements in a way that resulted in the manufacturing defect or injuries alleged here. Therefore, the Court grants Allergan's Motion to Dismiss as to Plaintiffs' causes of action for negligence and breach of implied warranty based on alleged defective manufacturing of the LAP-BAND.

Plaintiffs argue that dismissal would be premature without affording them "the opportunity to conduct extensive discovery of Allergan in order to determine what information was provided to the FDA." Mem. in Opp'n at 24. According to the affidavit of Plaintiffs' engineering expert, this discovery would involve, "[a]t a minimum," the following documents and issues: "the complete documentation submitted to the FDA by Allergan in order to obtain its PMA in 2001"; "all subsequent submissions to the FDA"; "any changes to [design and materials] specifications actually made or considered"; "whether there was ever an occasion for the manufacturer . . . to address any design or manufacturing issues"; "any complaints or other communications from customers or others . . . concerning the LAP-BAND product and any analysis which was made of these complaints or communications, including whether any such communications raised the issue (or should have raised the issue) of revisions in design, manufacturing or Instructions for Use (IFU)"; "any changes to the IFU made or considered after the original IFU was submitted to the FDA"; and the list goes on. Pls.' Ex. 2 at ¶¶ 11-12.

This is precisely the sort of fishing expedition the Supreme Court sought to avoid in requiring the plaintiff to plead facts demonstrating their entitlement to relief and the defendant's liability for misconduct. *See Twombly*, 550 U.S. at 559-60 ("[I]t is only by taking care to require allegations reach the level suggesting [the defendant's misconduct] that we can hope to avoid the

potentially enormous expense of discovery in cases with no 'reasonably founded hope that the [discovery] process will reveal relevant evidence' to support [the plaintiff's] claim." (quoting *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 347 (2005)); *Iqbal*, 556 U.S. at 686 (complainant "is not entitled to discovery" if "complaint is deficient under Rule 8"). "[A] district court must retain power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed." *Twombly*, 550 U.S. at 558 (quoting *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 528 n.17 (1983)). Plaintiffs cannot be permitted to pursue "extensive discovery" with nothing more than a series of conclusory allegations and an unfounded hope that the process will yield favorable facts. *See Iqbal*, 556 U.S. at 678-79 ("Rule 8 . . . does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions.").[7]

The Court holds that Plaintiffs fail to adequately plead any federal violation by Allergan in connection with any manufacturing defect in the LAP-BAND. Without sufficient pleading of a federal violation in the manufacture of the device, the Court cannot infer that Plaintiffs' negligence and implied warranty claims are premised on such a violation. Consequently, the Court cannot infer that these claims would not instead impose duties on Allergan in manufacturing the LAP-BAND that differ from or add to their federal requirements. Thus, in challenging as defective the manufacture of the LAP-BAND implant under Virginia law, Plaintiffs fail to plead parallel claims for negligence and breach of implied warranty. These

[7] Even in his dissent from the Eighth Circuit's decision to affirm dismissal in *Medtronic Leads II*, Judge Melloy emphasized that the discovery sought, which he would permit, was "quite limited"—specifically limited to the PMA submissions for the device at issue. *Medtronic Leads II*, 623 F.3d at 1209-10 (Melloy, J. concurring in part and dissenting in part). Also, in that case, the plaintiffs had alleged a specific manufacturing defect and identified federal standards that they believed were violated in connection with the defect. *See Medtronic Leads I*, 592 F.Supp.2d at 1153, 1157. Here, Plaintiffs have no comparable level of factual specificity in their pleading or comparable limit to the discovery they seek.

causes of action, as pled in the Amended Complaint, are therefore preempted by 21 U.S.C. § 360k(a) and must be dismissed under Rule 12(b)(6).

B. Breach of Express Warranty

The Court grants Allergan's Motion to Dismiss with respect to Plaintiffs' cause of action for breach of express warranty because Allergan's alleged warranties concern FDA approval of the LAP-BAND and the safety and effectiveness of the device. Without sufficient pleading of a federal violation by Allergan in manufacturing, labeling, or marketing the device, Plaintiffs' breach of express warranty claims are preempted by the MDA.

Under the Uniform Commercial Code, as adopted by statute in Virginia, "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." VA. CODE ANN. § 8.2-313(1)(a). Additionally, "[a]ny description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description." VA. CODE ANN. § 8.2-313(1)(b); *see also Kraft Foods N. Am., Inc. v. Banner Eng'g Sales, Inc.*, 446 F. Supp. 2d 551, 570 (E.D.Va. 2006). Such an express warranty is breached when the goods fail to conform to the affirmation of fact or description. *Kraft Foods*, 446 F. Supp. 2d at 572.

Claims for breach of express warranty are preempted by the MDA when they impose duties on the warrantor that differ from or add to federal requirements on medical devices that have obtained PMA. *See Bass*, 669 F.3d at 515 ("[E]xpress warranty claims cannot be used to impose requirements greater than that provided by the FDA regulations." (citing *Medtronic Leads II*, 623 F.3d at 1207); 21 U.S.C. § 360k(a). "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in [the

FDA-approved] design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety and effectiveness." *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). The MDA preempts express warranty claims that challenge the safety and effectiveness of a premarket approved device. *Desabio*, 817 F. Supp. 2d at 205; *see also Medtronic Leads II*, 623 F.3d at 1208. An express warranty claim that requires a factual finding that such a device was unsafe is preempted because "the safety and effectiveness of the [device] are matters solely for the FDA, and . . . the FDA determined that the [device was] safe and effective when granting PMA." *Medtronic Leads I*, 592 F. Supp. 2d at 1164; *see also Leonard v. Medtronic, Inc.*, Civil Action No. 1:10-CV-03787, 2011 WL 3652311, at *10 (N.D. Ga. Aug. 19, 2011) (a finding that the device is dangerous and unreliable "would directly conflict with the FDA's premarket approval of the device as reasonably safe and effective").

Similarly, the MDA preempts express warranty claims that challenge "FDA-approved representations made by the manufacturer." *Horowitz*, 613 F. Supp. 2d at 285; *see also Parker*, 584 F. Supp. 2d at 1303. In order to succeed, such express warranty claims require "a finding that a defendant violated state law by not living up to FDA-approved promises," which "would necessarily conflict with the FDA's determination that the label was not false or misleading." *Desabio*, 817 F. Supp. 2d at 206 (citing *Leonard*, 2011 WL 3652311, at *11). In this way, express warranty claims would employ state law to "impose additional and different requirements that would necessarily disrupt the federal scheme . . . ." *Desabio*, 817 F. Supp. 2d at 206; *see also Horowitz*, 613 F. Supp. 2d at 285 (Express warranty claims challenging FDA-approved representations about the device "would contradict the FDA's determination that the representations made on the label were adequate and appropriate and, thus, impose requirements different from or in addition to the federal requirements.").

However, a claim for breach of express warranty claim would not be preempted to the extent that it is based on representations made by the manufacturer about the device that were not approved by the FDA. Such a claim would not impose duties or requirements on the manufacturer that differ from or add to federal requirements because the challenged representations would lie beyond the scope of those representations approved by the FDA. Thus, "[i]n order to avoid preemption, the plaintiff's breach of express warranty claim must 'identify representations of the manufacturer which exceed the scope of the FDA approved statements, thereby establishing a contractual obligation voluntarily entered into by the manufacturer.'" *Horowitz*, 613 F. Supp. 2d at 285 (quoting *Lake v. Kardjian*, 22 Misc.3d 960, 963 (N.Y. Sup. Ct. 2008)).

Here, Plaintiffs' cause of action for breach of express warranty does not survive MDA preemption because the representations about the LAP-BAND alleged to constitute express warranties all concern the premarket approval of the LAP-BAND and the FDA's determination that the device is safe and effective. Plaintiffs allege that Allergan made four misrepresentations about the LAP-BAND that were "part of the basis of the bargain": (a) "the LAP-BAND would be manufactured in accordance with FDA regulations"; (b) "the LAP-BAND would be safe and effective"; (c) "the LAP-BAND would not deviate materially from the device that received FDA approval"; and (d) "the LAP-BAND would not malfunction while in use." Am. Compl. ¶ 88.

Breach of express warranty claims based on these representations ultimately challenge the FDA's safety and effectiveness determination as well as federal requirements on the manufacture and labeling of the device. The manufacture of the LAP-BAND is subject to FDA regulation and cannot "deviate materially" from the specifications approved by the FDA as part

of its PMA. As noted previously, Plaintiffs fail to plead any violation of FDA regulations by Allergan in the manufacture of the LAP-BAND.

Additionally, Plaintiffs do not allege that any of the alleged warranties made by Allergan were made in violation of FDA restrictions on the labeling and marketing of the LAP-BAND. Express warranty claims that challenge FDA-approved representations about the LAP-BAND would employ Virginia law to impose requirements on Allergan that differ from requirements imposed by the FDA. Given the FDA's premarket approval of the LAP-BAND, the Court infers that statements concerning the device's FDA approval, safety, and effectiveness are FDA-approved representations about the device. Therefore, Plaintiffs' express warranty claims, as pled, fall directly within the preemption provision of 21 U.S.C. § 360k(a).

For these reasons, the Court holds that Plaintiffs' express warranty claims are preempted and grants Allergan's Motion to Dismiss as to the cause of action for breach of express warranty.

C. Fraud by Negligent Misrepresentation and Failure to Disclose

The Court grants Defendant's Motion to Dismiss with respect to Plaintiffs' causes of action for fraud by negligent misrepresentation and nondisclosure. The negligent misrepresentation claims must be dismissed for Plaintiffs' failure to plead the contents and circumstances of the alleged misrepresentations with particularity. To the extent that it is based on representations that have been approved by the FDA, the cause of action for negligent misrepresentation is preempted by the MDA. The cause of action for fraud by nondisclosure is also preempted by the MDA because it would impose requirements under Virginia law that add to federal requirements on statements Allergan can make concerning the LAP-BAND.

"To prevail on an actual fraud claim under Virginia law, a plaintiff must prove by clear and convincing evidence '(1) a false representation (2) of a material fact (3) made intentionally and knowingly (4) with intent to mislead, (5) reliance by the party mislead, and (6) resulting

damage to the party misled.'" *Hitachi Credit Am. Corp. v. Signet Bank*, 166 F.3d 614, 628 (4th Cir. 1999) (quoting *Evaluation Research Corp. v. Alequin*, 439 S.E. 2d 387, 390 (Va. 1994)). Under Rule 9(b), a party alleging fraud "must state with particularity the circumstances constituting fraud." FED. R. CIV. P. 9(b). "[T]he 'circumstances' required to be pled with particularity under Rule 9(b) are 'the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby.'" *Harrison*, 176 F.3d at 784.

Fraud and failure to warn claims based on state law that would impose warning and disclosure duties on manufacturers of medical devices that are different from or in addition to FDA-mandated warnings are preempted by the MDA. *See Riegel*, 552 U.S. at 330. In *Medtronic Leads II*, the Eighth Circuit considered the plaintiffs' contention that the manufacturer of an FDA premarket approved medical device was required by state law to give warnings in addition to those required by the FDA. *Medtronic Leads II*, 623 F.3d at 1204. The court held that this requirement was "precisely the type" of state-law requirement that is different from or in addition to federal requirements, specifically the requirements of the FDA's PMA process, and was therefore preempted. *Id.* at 1205. In *Horowitz*, the district court assessed a failure to warn claim attacking a premarket approved product label. *Horowitz*, 613 F. Supp. 2d at 286-87. The court explained that "[a]llowing [such a] claim to proceed would permit a jury to find that [the marketer of the device was] required 'to provide warnings above and beyond those on . . . a label that was specifically approved by the FDA as part of the PMA process.'" *Id.* (quoting *Medtronic Leads I*, 592 F. Supp. 2d at 1159). Therefore, the failure to warn claim imposed requirements different from or in addition to the federal regulations and was preempted. *Horowitz*, 613 F. Supp. 2d at 287.

Here, first, Plaintiffs' cause of action for negligent misrepresentation must be dismissed for their failure to meet pleading requirements for fraud allegations set forth in Rule 9(b). In the Amended Complaint, Plaintiffs fail to allege with particularity the "time, place, and contents of the false representations, [and] the identity of the person making the misrepresentation[s.]" *Harrison*, 176 F.3d at 784. Most of Plaintiffs' allegations about Allergan's misrepresentations are made "[u]pon information and belief" and fail to state the particular contents of those misrepresentations. Plaintiffs allege that statements made by Allergan in advertising and promotional materials for the LAP-BAND were "false" and "deceptive" and "inadequately informed [Ms. Ali] of potential risks . . . related to the LAP-BAND and the LAP-BAND surgery." Am. Compl. at ¶¶ 36-38. The contents of the alleged misrepresentations that support Plaintiffs' negligent misrepresentation claims are never described. Pleading of the circumstances in which these alleged misrepresentations were made is also inadequate. Plaintiffs allege that the misrepresentations were made on "websites, . . . presented at medical and and professional meetings, . . . disseminated by sales representatives, [and made in] reports, press releases, advertising campaigns, television commercials, print advertisements," *et cetera*. Am. Compl. at ¶ 45. This allegation fails to provide the particular time and place of the alleged fraud, as required under Rule 9(b), and therefore Plaintiffs' cause of action for negligent misrepresentation must be dismissed. *See Harrison*, 176 F.3d at 784; FED. R. CIV. P. 9(b).

Second, Plaintiffs' negligent misrepresentation cause of action is preempted by the MDA to the extent that it is based on representations approved by the FDA. Any fraud claims that challenge FDA-approved representations about the LAP-BAND would employ Virginia law to impose requirements on Allergan that differ from requirements imposed by the FDA. Such claims for misrepresentation would fall directly within the preemption provision of 21 U.S.C. §

360k(a). For this reason, any such negligent misrepresentation claims by Plaintiffs are preempted and cannot survive Allergan's Motion to Dismiss.

Third, Plaintiffs' cause of action for fraudulent nondisclosure is preempted by the MDA as well. Any claim by Plaintiffs that, under Virginia law, Allergan was required to provide disclosures and warnings about the LAP-BAND that were not required by the FDA necessarily adds to federal requirements for disclosures and warnings about the LAP-BAND. Such a claim would impose "precisely the type of state requirement[s] that [are] 'different from or in addition to' the federal requirement[s] and [are] therefore preempted." *Medtronic Leads II*, 623 F.3d at 1205. This claim must be dismissed.

Finally, any fraud claims by Plaintiffs challenging Allergan's alleged nondisclosure of facts that the LAP-BAND was not safe and effective, or challenging representations that the LAP-BAND was safe and effective, would require a finding that the device was not safe or effective. Any such fraud claims would therefore challenge the FDA's determination, through the rigorous PMA process, that the device was safe and effective, and the FDA's ultimate approval of the device. In order to withstand MDA preemption, such claims must be premised on some violation by Allergan of federal manufacturing requirements on the LAP-BAND, which Plaintiffs fail to plead adequately.[8] For this reason, any fraud claims challenging the safety and effectiveness of the LAP-BAND are preempted and must be dismissed.

Thus, Plaintiffs' causes of action for fraudulent nondisclosure and negligent misrepresentation, as pled in the Amended Complaint, fail for preemption under 21 U.S.C. § 360k(a) and insufficient pleading under Rule 9(b).

D. Violations of Virginia Consumer Protection Act

[8] *See* discussion *supra* Part I.A.

The Court grants Allergan's Motion to Dismiss as to Plaintiffs' claims brought under the Virginia Consumer Protection Act ("VCPA") for two reasons. First, the VCPA exempts transactions in prescription medical devices regulated by the FDA. Second, recovery on any VCPA claims challenging FDA-approved statements about the LAP-BAND would impose requirements on Allergan different from or in addition to requirements imposed by the FDA. Such claims are expressly preempted by the MDA.

The Virginia General Assembly enacted the VCPA "as remedial legislation to promote fair and ethical standards of dealings between suppliers and the consuming public." VA. CODE ANN. § 59.1-197. The Act prohibits suppliers from engaging in various "fraudulent acts or practices," including "[m]isrepresenting that goods or services have certain quantities, characteristics, ingredients, uses, or benefits;" and "[u]sing any other deception, fraud, false pretense, false promise, or misrepresentation in connection with a consumer transaction . . . ." VA. CODE ANN. § 59.1-200(A)(5), (A)(14). By its own terms, however, the VCPA does not apply to "[a]ny aspect of a consumer transaction which aspect is authorized under laws or regulations of this Commonwealth or the United States, or the formal advisory opinions of any regulatory body or official of this Commonwealth or the United States." VA. CODE ANN. § 59.1-199(A).

Plaintiffs' VCPA claim fails because it challenges conduct that is expressly excluded from the scope of the VCPA. Plaintiffs base their VCPA cause of action on representations made by Allergan about the LAP-BAND in advertisements and other marketing materials concerning the safety and effectiveness of the device. Representations about the LAP-BAND in marketing materials for the device are authorized and regulated by the FDA under federal law. The VCPA, therefore, does not apply to it, *see id.*, and therefore no action challenging Allergan's marketing

practices with respect to the LAP-BAND may be brought under the VCPA. For this reason, Plaintiffs' VCPA claim must be dismissed with prejudice.

Even if the VCPA provided for the cause of action asserted in the Amended Complaint, such a cause of action would be preempted by the MDA to the extent that it is based on representations about the LAP-BAND that have been approved as part of its PMA. Like Plaintiffs' fraud claims, any VCPA claims challenging FDA-approved statements about the LAP-BAND would utilize the statute to impose requirements on Allergan that differ from or add to requirements imposed by the FDA. Such statutory claims fall directly within the preemption provision of 21 U.S.C. § 360k(a) and must be dismissed.

For these reasons, the Court grants Allergan's Motion to Dismiss as to Plaintiffs' VCPA claims and dismisses these claims with prejudice.

E. Violation of Virginia's False Advertising Statute

The Court grants Allergan's Motion to Dismiss with respect to Plaintiffs' cause of action for false advertising because Plaintiffs fail to identify any false promise or statement of fact made in an advertisement by Allergan that was not approved by the FDA. To the extent that Plaintiffs' false advertising cause of action is based on FDA-approved representations about the LAP-BAND, it is preempted by the MDA and must be dismissed.

Section 59.1-68.5 of the Virginia Code provides a private cause of action for "[a]ny person who suffers loss as the result of" a violation of Virginia's statute prohibiting false advertising. VA. CODE ANN. § 59.1-68.5. Section 18.2-216 prohibits the publication and dissemination of "an advertisement of any sort regarding merchandise . . . which advertisement contains any promise, assertion, representation or statement of fact which is untrue, deceptive or

misleading" with "the intent to increase the consumption of [the merchandise.]" VA. CODE ANN. § 18.2-216.

Plaintiffs' cause of action for violations of Virginia's false advertising statute fails for inadequate pleading and, to the extent that it challenges FDA-approved representations, preemption by the MDA. The Court recognizes that, in Paragraph 123 of the Amended Complaint, Plaintiffs incorporate into their false advertising cause of action all allegations made in connection with their fraud, warranty, and VCPA causes of action. Throughout the Amended Complaint, Plaintiffs allege that Allergan made many promises and representations about the LAP-BAND that they allege were false. However, the only statements Plaintiffs identify has having been made in advertisements are those set forth in Paragraph 116(a) in connection with Plaintiffs' VCPA cause of action. According to Plaintiffs, Allergan made statements in its advertisements for the LAP-BAND that included the following:

> "Now is for [*sic*] putting the yo-yo dieting madness behind you. Now is for [*sic*] LAP-BAND"; "You've been let down by countless diets and weight-loss programs, so no [*sic*] it's time for a tool that can work"; "Diets Fail – The LAP-BAND Works"; LAP-BAND can help you take off weight – and keep it off" and that LAP-BAND surgery is "Safe" . . .

Am. Compl. at ¶ 116(a). To the extent that the challenged advertising statements can be construed as promises or statements of fact, such that they fall within the scope of § 18.2-216, they can only be construed as representations that the LAP-BAND is safe and effective. As such, without any pleading to the contrary, the Court infers that these statements have been approved by the FDA as part of its PMA of the LAP-BAND. Any false advertising claims Plaintiffs might assert based on these statements are preempted by the MDA for the same reasons set forth in the

Court's analysis of Plaintiffs' express warranty, fraud, and VCPA claims.[9] Therefore, the Court grants Allergan's Motion to Dismiss as to Plaintiffs' false advertising claims.

IV. CONCLUSION

The Court grants Allergan's Motion to Dismiss Amended Complaint. First, the Court dismisses without prejudice Plaintiffs' causes of action for negligence and breach of implied warranty. The Amended Complaint does not contain adequate pleading of any federal violation by Allergan in connection with a manufacturing defect in the premarket approved medical device at issue in this case.

Second, the Court dismisses without prejudice Plaintiffs' claims for breach of express warranty. The express warranties pled in Paragraph 88 of the Amended Complaint concern FDA approval of the device and statements about the device's safety and effectiveness. Without sufficient pleading of any federal violation by Allergan in making these statements or in the manufacture of the device, any claim for breach of express warranty based on these statements is preempted by the MDA.

Third, the Court dismisses without prejudice Plaintiffs' causes of action for negligent misrepresentation and nondisclosure. Plaintiffs fail to plead the contents and circumstances of Allergan's alleged misrepresentations with particularity. To the extent that Plaintiffs' negligent misrepresentation claims are based on FDA-approved statements, these claims are preempted by the MDA because they would impose requirements under Virginia law that differ from federal requirements concerning the LAP-BAND device. The cause of action for fraud by nondisclosure is preempted by the MDA because it would impose requirements under Virginia law that add to federal requirements on statements Allergan can make about the device.

[9] *See* discussion *supra* Parts I.B, I.C, & I.D.

Fourth, the Court dismisses with prejudice Plaintiffs' Virginia Consumer Protection Act ("VCPA") cause of action because the VCPA exempts transactions in prescription medical devices regulated by the FDA. Additionally, without sufficient pleading of any federal violation in the manufacture or marketing of the device, recovery on any VCPA claims challenging FDA-approved statements about the LAP-BAND are preempted by the MDA.

Finally, the Court dismisses without prejudice Plaintiffs' cause of action for false advertising under Virginia's false advertising statute. The Court infers that this cause of action, as pled, is based on FDA-approved representations about the safety and effectiveness of the device. Without sufficient pleading of any federal violation in making these representations about the device or in the manufacture of the device, Plaintiffs' false advertising claims are preempted by the MDA.

An appropriate order will issue.

ENTERED this 23rd day of August, 2012.

Alexandria, Virginia

8/23/12

/s/
Gerald Bruce Lee
United States District Judge